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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/166,298	10/05/98	KIM K	P1092R1

HM22/0522

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 05/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/166,298	Kim et al.
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Apr 24, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-12* is/are pending in the applicat

Of the above, claim(s) *7, 8, 11, and 12* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6, 9, and 10* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's amendments filed 4/24/00 (Papers No. 8 and 9) are acknowledged and have been entered.

Claims 1-12 are pending.

Applicant's election of the species--- antibodies which block binding of IFN-αD to INFAR2, the mAb 1D3, and anti-INFAR2 mAb that binds to one or more amino acid positions 133, 134, 135 and 139 in situ in the extracellular domain of IFNAR2 --- in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7, 8, 11 and 12 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected species.

Claims 1-6 and 9-10 are being examined presently.

The invention being examined is an anti-IFNAR2 mAb, 1D2, which blocks the binding of IFN-αD and which binds to one or more amino acid positions 133, 134, 135 and 139 in situ in the extracellular domain of IFNAR2.

2. It is noted that this application appears to claim subject matter disclosed in prior copending Application No. 60/061,185 filed 10/06/97. Although a reference to the prior application was be inserted as the first sentence of the specification of this application, the statutory reference included in this statement refers to 35 USC 119 not to 35 USC 119(e). Applicant is required to amend said statement to refer to 35 USC 119(e). See 37 CFR 1.78(a).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the hybridomas known as 1D3, 1F3 and 3B7 are required to practice the claimed invention as recited in claims 5 and 10. As required elements, they must be known and readily available to the public or obtainable by a repeatable

method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the instant hybridomas. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the monoclonal antibodies known as 1D3, 1F3 and 3B7. The claims read on specific antibodies produced by specific deposited hybridomas that would have specific properties of the particular clone or subclone that was deposited at the time of deposit. Deposit of the hybridomas producing said antibodies would satisfy the enablement requirements of 35 U.S.C. 112.

In addition, the identifying information set forth in 37 CFR 1.809 (d) should be added to the specification. See 37 CFR 1.801-1.809 for additional explanation of these requirements. The requirements under 37 CFR 1.808 can be met by submission of an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability of the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 5, 6 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 5 and 10 are indefinite in the recitation of "1D3, 1F3 and 3B7" because their characteristics are not known. The use of "1D3, 1F3 and 3B7" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "1D3, 1F3 and 3B7" are merely laboratory designations which do not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct monoclonal antibodies, cell lines or hybridomas.

b. Claim 6 is indefinite because it is not clear whether the claimed antibody binds to only one set of the recited positions or to more than one set of the recited positions.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1- 6, 9 -11 are rejected under 35 U.S.C. 102(b) as being anticipated by Chuntharapai et al (FASEB J, 4/30/1996, Vol. 10(6), PPA1325, Abstract 1877) as evidenced by Chuntharapai et al (J. Immunol. Vol. 163, pages 766-773, 1999).

Chuntharapai et al (FASEB J) teach the anti-IFNAR monoclonal antibody 1D3. It is an inherent property of 1D3 that it meets all the limitations of the instant claims as evidenced by Chuntharapai et al (J. Immunology). ID3 is an IgG2a isotype monoclonal antibody (especially Table 1, line 1) that blocks the binding of IFN-α1(IFN-αD), IFN-α2, IFN-α5 and IFN-α8, but not IFN-β (especially page 768, column 2, lines 34-41). ID3 recognizes an epitope (especially page 768, column 2, lines 6-10) spanning amino acid residues 133-139 and 153-157 (especially Table IV, page 769 column 2, lines 1-2). Instant claim 5 is included because the IF3 monoclonal antibody taught by Chuntharapai et al (FASEB J) recognizes a conformational epitope which includes amino acid residues 133-139 and 153-156 as evidenced by Chuntharapai et al (J. Immunology, page 769, last four sentences of column 1).

The reference teachings anticipate the claimed invention.

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 1-6 and 9-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 9-10 of copending Application No. 08/943,771. This is a provisional double patenting rejection since the conflicting claims have not in fact patented.

11. No claim is allowed.

12. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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